K070891

JUN 11 2007

PREMARKET NOTIFICATION 510(K) SUMMARY

Company:

Altiva Corporation
9800 Suite i, Southern Pines Blvd
Charlotte, NC 28273
Telephone: 704/409-1754
Fax: 704/409-1771

Company Contact:

John Kapitan
Vice President, Product Development and RA/QA

Date:

March 27, 2007

Trade Name:

Altiva® Classic ACP System

Common Name

Spinal Intervertebral Fixation Orthosis

Classification:

Orthopedics, 888.3060, Class II

FDA Product Code ;

KWQ

Device Description:

The Altiva Classic ACP System is an anterior screw fixation system for the cervical spine. It includes titanium alloy plates and screws which are provided clean and non-sterile. Various sizes of the implants are provided.

Intended Use:

The Altiva Classic ACP System is intended for anterior screw fixation to the cervical spine (C2 to C7). The system is intended for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined by kyphosis, lordosis, or scoliosis), pseudoarthrosis, and failed previous fusion.

Predicate Device:

Predicate device information is included.

Performance Data:

Performance data were submitted to characterize the Altiva Classic ACP System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Altiva Corporation
% Mr. John Kapitan
VP, Product Development, RA/QA
9800 Southern Pines Boulevard
Charlotte, North Carolina 28273

JUN 11 2007

Re: K070891
Trade/Device Name: Altiva® Classic ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 26, 2007
Received: March 30, 2007

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.
f/t:SJB:afb:6/4/07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

Indication for Use Statement

510(k) Number (if known): K070891

Device Name: Altiva® Classic ACP System

Indications for Use:

The Altiva Classic ACP System is intended for anterior screw fixation to the cervical spine (C2 to C7). The system is intended for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined by kyphosis, lordosis, or scoliosis),
- pseudoarthrosis, and
- failed previous fusion.

Prescription Use X or Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070891